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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,989	03/30/2006	Heinz Von Der Kammer	37998-237373	9161

26694 7590 06/25/2008

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EXAMINER	
HIRIYANNA, KELAGINAMANE T	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
06/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,989	VON DER KAMMER ET AL.	
	Examiner	Art Unit	
	KELAGINAMANE T. HIRIYANNA	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/03/2008 has been entered.

Applicant's response filed on 04/03/2008 in response to office action mailed on 10/03/2007 has been acknowledged.

Claims 11 and 12 are amended.

Claims 1-11 and 13-30 are cancelled.

Claims 11 and 12 *are pending and are examined in this office action.*

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is ***571-273-8300.***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The Applicants arguments in the response filed on 04/03/2008 are fully considered while writing this action.

Withdrawn the rejection of claims 11-13, 16, and 29 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reason of record as set forth in the previous office action mailed on 04/10/2007 in view of applicants amendments to claims narrowing the breadth of claims by limiting to SEQ ID NO:1 and 2.

Withdrawn the rejection of claims 11-13, 16, 25-26 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening for a modulator of SULT4A1 activity in an isolated cell or using a

SULT4A1 transgenic or SULT4A1 gene disrupted Drosophila or a mouse, does not enable a modulation of any neurodegenerative disease in any animal, does not enable modulation of any SULT4A1 variants by using any methods for the reason of record as set forth in the previous office action mailed on 04/10/2007 with respect to breadth of claims in view of applicants amendments to claims narrowing the breadth of claims by limiting number of molecules used for test compound screening to SEQ ID NO:1 and 2 and to animals screened to mouse or drosophila Alzheimers models and further in view of the new rejections below.

Notice To Comply

With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Specifically the application fails to comply with CFR 1.821(d), which states:
(d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing " in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application (see MPEP 2422.03).

For compliance with sequence rules, it is necessary to include the sequence in the "Sequence Listing" and identify them with SEQ ID NO. In general, any sequence that is disclosed and/or claimed as a sequence, i.e., as a string of particular bases or amino acids, and that otherwise meets the criteria of 37 CFR 1.821(a), must be set forth in the "Sequence Listing." (see MPEP 2422.03).

The instant specification fails to comply with the requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures because: The application claims SEQ ID NO:1 and SEQ ID NO:2 as the protein molecules where as the CRF of the application identifies the SEQ IDNO:1 & 2 as artificial PCR (nucleic acid) primers.

Further the figures in the text identifying SEQ ID NOs: 1 and 2 do not correspond to the sequences represented in CRF bearing same SEQ ID NOs.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification

For the response to this office action to be complete, Applicants are required to comply with the Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Withdrawn the rejection of claims 11-13, 16, and 29 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reason of record as set forth in the previous office action mailed on 04/10/2007 in view of applicants amendments to claims narrowing the breadth of claims by limiting to SEQ ID NO:1 and 2.

Withdrawn the rejection of claims 11-13, 16, 25-26 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening for a modulator of SULT4A1 activity in an isolated cell or using a SULT4A1 transgenic or SULT4A1 gene disrupted Drosophila or a mouse, does not enable a modulation of any neurodegenerative disease in any animal, does not enable modulation of any SULT4A1 variants by using any methods for the reason of record as set forth in the previous office action mailed on 04/10/2007 with respect to breadth of claims in view of applicants amendments to claims narrowing the breadth of claims by limiting number of molecules used for test compound screening to SEQ ID NO:1 and 2 and to animals screened to mouse or drosophila Alzheimers models and further in view of the new rejections below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 12 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph for the SEQ ID NO: 1 and 2 in the CRF not being what applicant claims i.e., a translation product of the gene coding for a cytosolic SULT4A1.

(New) Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Claims *11 and 12* are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The scope of invention as claimed encompasses SEQ ID NO:1 and SEQ ID NO: 2 as representing a translation product of the gene coding for a cytosolic sulfotransferase family 4A member 1 whose expression levels as an indicator or diagnostic molecule in screening for modulators of Alzheimers disease.

The CRF for SEQ ID NO:1 and SEQ ID NO: 2 provided in the specification at best teaches them to be short oligonucleotide sequences of about 21-25 nucleotides.

The application does not teach via its CRF, that is used for searching purposes, that the SEQ ID NO:1 and SEQ ID NO: 2 represent any translation product of a cytosolic sulfotransferase family 4A member 1.

Applicant is referred to the guidelines for ***Written Description Requirement*** published January 5, 2001 in the Federal Register, Vol.66, No.4, pp.1099-1110 (see <http://www.uspto.gov>). The lack of disclosure in the specification is not deemed sufficient to reasonably convey to one skilled in the art that the applicants were in

possessions of the Sequences of proteins and nucleic acids recited in the claims at the time the application was filed. In the absence of proper disclosure one of skill in the art would conclude that applicant was not in possession of the claimed species.

Claims 11 and 12, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of screening for a modulator of SULT4A1 activity in an isolated cell or using a SULT4A1 transgenic or SULT4A1 gene disrupted Drosophila or a mouse, does not enable a modulation of any SULT4A1 variants as represented SEQ ID NO: 1 and 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

.Response to Arguments of 04/03/2008:

The Applicant amends claims 11& 12 and cancels other claims to restrict diagnostic molecules used for screening a modulator of Alzheimers disease to to SEQ ID NO.1 and SEQ IDNO:2 and argues that as amended the instant claims should overcome the rejection. The Applicant further argues that the Farb reference does not teach method of screening for a modulator of Alzheimers disease.

Applicants amendments and arguments are however found not persuasive firstly because the SEQ ID No: 1 & 2 in CRF are found not representing any variant form of SULT4A1 polypeptide but instead found to be short oligomers of nucleic acid. Since these oligomers do not represent a molecule that is diagnostic of the expression level of the claimed SULT4A1 polypeptide variant, the invention is not enabled as claimed.

Claim Rejections - 35 USC § 102

Claims 11 and 12 stand rejected under 35 USC 102 (b) as being anticipated by Farb et al., (WO 02/18541) for the reason of record as set forth in the previous office action mailed on 10/03/2007.

The above claims are directed to a method for screening for a modulator of Alzheimers associated with SULT4A1 gene, transcript, protein or derivatives and variants thereof by contacting a cell or animal with a test compound and measuring the

alteration in the level of activity or said SULT4A1 or level of said SULT4A1 gene, transcript, protein or derivatives and variants thereof.

.**Response to Arguments of 04/03/2008:**

The Applicant amends claims 11& 12 and cancels other claims to restrict diagnostic molecules used for screening a modulator of Alzheimers disease to to SEQ ID NO.1 and SEQ IDNO:2 and argues that as amended the instant claims should overcome the rejection. The Applicant further argues that the Farb reference does not teach method of screening for a modulator of Alzheimers disease.

Applicants amendments and arguments are however found not persuasive firstly because the SEQ ID No: 1 & 2 in CRF are found not representing any variant form of SULT4A1 polypeptide but instead found to be short oligomers of nucleic acid. Hence the current rejection is maintained with respect to the original claim to SULT4A1 polypeptide.

Farb reference clearly teaches method of treating (modulating) Alzheimers disease comprising administering SULT4A1 polypeptide (modulator). The said modulator increases the sulfotransferase activity when provided to a cell (p.41, paragraphs 2-3). Further Farb clearly teaches method of measuring SULT4A1 sulfotransferase enzyme and its expression by its ability to bind PAP-Agarose and by its activity to form sulfate groups on small neuro-chemicals (p.4, lines 1-27). The cited art thus anticipates the invention as claimed. Hence the rejection is maintained.

Conclusion:

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna Ph.D.,* whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Friday from 9 AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.*, may be reached at **(571) 272-0739.** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see

http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

Kelaginamane T. Hiriyanna

Patent Examiner

Art Unit 1633

/Robert M Kelly/

Examiner of Art Unit 1633

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/573,989	VON DER KAMMER ET AL.	
	Examiner	Art Unit	
	KELAGINAMANE T. HIRIYANNA	1633	